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DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamiaca, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 29, 2003

Richard R. McClenning
President
Premier Dairy Service LLC
1048 State Route 197
Argyle, NY 12809

Ref: NYK-2003-33

Dear Mr. McClenning:

During an inspection of your drug manufacturing facility located in Argyle, New York, conducted between the dates of June 17, 2003 and June 23, 2003, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211). Such deviations cause the drug products, ready to use iodine teat sanitizers for cows manufactured by your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. The master production and control record, reconstitution form, used for reconstituted 1% iodine teat sanitizer batches does not include an appropriate specification for percent iodine [21 CFR 211.100(a) and 211.186(b)(9)]. The specification is recorded as 0.44%-0.56% which is the specification for the 0.5% iodine teat sanitizer.

2. Failure to document satisfactory conformance to appropriate specifications prior to release of drug batches [21 CFR 211.160(b) and 211.165]. Records for batches of reconstituted 1% iodine teat sanitizer report test results for percent iodine that do not meet appropriate specifications. For example, batches, #'s C2L1732B and C3B0116C mixed during January through May 2003 are reported to be below an appropriate specification range for percent iodine for reconstituted 1% iodine teat sanitizer. The test results were within the range for the 0.5% batches.

3. Failure to test incoming iodine teat sanitizer concentrate to verify identity [21 CFR 211.84(d) (1)].

4. Failure to label reconstituted iodine teat sanitizer with an expiration date [21 CFR 211.137]. During the inspection our investigator observed the labeling on containers of reconstituted iodine teat sanitizer, lot # C3B0251C, to lack an expiration date.

5. Failure to follow written procedures for the cleaning of drug product containers [21 CFR 211.94]. The cleaning of retrieved containers for reuse for reconstituted iodine teat sanitizer has not been documented, since January 2003, on the cleaning log.

6. Failure to follow procedures used to reconcile the quantities of labeling issued, used and returned [21 CFR 211.125]. There were no entries on the label log for 0.5% iodine teat sanitizer after September 2002. There was no label log for 1% iodine teat sanitizer.

The above identification of violations and the observations on the form FDA-483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. As a manufacturer of veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,

Robert L Hart

Jerome G. Woyshner
District Director